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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,280	11/24/2004	David Mainwaring	4145-20	7548

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EXAMINER	
LILLING, HERBERT J	
ART UNIT	PAPER NUMBER
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,280	MAINWARING ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10-06-2004 (Prelim Amd)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Attachment US 5,266,479*.

1. Receipt is acknowledged of the preliminary amendment, prior art information disclosure statement and certified copy of the foreign priority application filed October 06, 2004 and the prior art information disclosure statement filed June 08, 2006 for this application which is a 371 of PCT/EP03/03631 filed April 08,2003 which claims benefit to UK 02080414 filed April 08, 2002 and US 60411751 filed September 19, 2002.

2. Claims 1-12 are present in this application.

DETAILED ACTION

3. Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-5, **drawn to a method of producing a product protein,** wherein the protein is expressed from a mammalian cell in cell culture at least during a certain span of time during cell culture, comprising the steps:
a) preparing a cell culture medium for culturing mammalian cells, preferably preparing a cell culture medium that is devoid of butyrate,
b) and further adding acetic acid or an acetate salt or an acetyl ester to a final concentration of from 1 to 20 mM,
c) further culturing said cell in said medium with concomittant expression of product protein,
d) and finally harvesting said protein from the cell culture..

Group II, claims 6-9, **drawn to a product cell culture medium** for animal cell culture, comprises acetic acid or an acetate salt or a biologically activated acetyl ester at a concentration of from 1 to 20 mM, and preferably is devoid of butyric acid or any of its salts.

Group III, claim 10, **drawn to a second product** which is either a solid or a liquid, which is a medium concentrate for preparation of a culture medium as defined in claim 6.

This claim cannot be properly classified, as the concentrate is not defined as to the scope of the solid or liquid components.

Claim 11 is a non-statutory claim.

Group IV, claim 12, is **drawn to a third product** for a cell culture comprising mammalian cells in a medium according to claim 6.

The inventions are independent or distinct, each from the other because:

Invention II does not require the specifics of Invention I.

Invention I does not require the specifics of Invention II.

Invention I is drawn to a process for preparing a protein product which requires "a preparing a cell culture medium as noted by step (a); whereas Invention II is drawn to a product culture that requires the cell culture medium to have a specific concentration of acetic acid, acetate salt or a biologically activated acetyl ester that is preferably devoid of butyric acid or any of its salts. Invention I am preferably devoid of butyrate.

Invention III is drawn to a product of a liquid or solid that does not have any properties which concentrate can be any concentrate, thus lacks the single general inventive concept.

Invention IV lacks the single general concept under PCT Rule 13.1 that the inventions or groups of inventions which are not so linked as to form a single general

inventive concept under PCT Rule 13.1 by the disclosure of US Patent 5,266,479 which teaches a cell culture medium within the scope of the claimed subject matter for the cell culture:

> "
>
> at a concentration of from 0.01 to about 1.0 mg/l; ergocalciferol at a concentration of from about 0.01 to about 0.5 mg/l; and linoleic acid or its ester at a concentration of from about 0.01 to about 1.0 mg/l."

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, the inventions have acquired a separate status in the art due to their recognized divergent subject matter and there would also be an extreme ersiou burden to search and examine the various different inventions due to the different strategies required for any computerized search, thus the restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species:

A. Whereby the process or product cell culture comprises adding or contains:

a. acetic acid

If species (a) is elected there is a further election as when the acetic acid is added:

aa> prior to starting the cell culture;

ab> directly to the cell culture.

b. an acetate salt

i. alkali metal acetate;

ii. alkaline earth metal acetate;

If species (b) is elected there is a further election as when the acetate whether it is species i. or species ii. is added:

bai or baii> prior to starting the cell culture;

bbii or bbii> directly to the cell culture.

c. an acetyl ester

d. combination of the above-please specify the specific combination and whether the acetic acid or acetate is added prior to or directly to starting the cell culture.

B. Whereby the mammalian cells are selected from:

a. lymphoid cells;

ai. NSO cells

air> recombinant cells;

ain> non-recombinant cells.

b. any other cells which includes SV-40 immortalized monkey kidney cells (COS-7) cells; canine kidney cells (MDCK),african green monkey kidney cells (VERO-76),baby hamster kidney (BHK) cells, human liver cells (Hep G2), or other-please specify the specific cells.

If b is selected-the selected specific cells whether the cells are:

bir> recombinant cells;

bin> non-recombinant cells.

C. Whereby the culture medium is :

a. serum-free;

b. protein-free;

c. serum-free and protein-free;

d. not serum-free;

e. not-protein free;

f. not serum-free and not protein-free;

D. Whereby the medium concentrate is:

a. solid;

b. liquid.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic to all of the above species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention I-IV and an election for each of the requires species A-D [e.g., which includes one species from Aa or Ab or Ac or Ad, and further if Aa is elected to elect a subspecies as noted as Aa-ai or Aa-aii etc] to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

It is specifically noted that Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.**

If Applicant requires any assistance, it is strongly suggested that Applicant contact this Examiner for assistance to clarify any requirements for the above restriction or election.

7. It is noted that claims which contain broad claimed limitation language as well as narrower claimed limitations would probably be rejected. All of the claims would probably be rejected for e.g claim 1 "**preferably p**reparing a cell culture medium that is devoid of butyrate, and further **preferred** preparing a cell culture medium allowing for growth of the mammalian cells, **more preferably** a protein-free cell culture growth medium,". It is suggested that to avoid any possible rejection(s) for the above language, Applicant cancel the subject matter and submit dependent claims to avoid any rejection based on the following requirement:

> A **broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite**, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claimx recites the broad recitation x, and the claim also recites xx which is the narrower statement of the range/limitation.

The same problem in claim 1 part (a) as well as in claim 1 parts (b) and (c); claim 4; claim 6; claim 8; claim 9 and claim 12.

The above suggestion is not a requirement. Applicant is required only to elect an invention and species as noted in the above paragraphs.

8. In accordance with this Tech Center 1600 Policy pertaining to rejoinder of claims Applicant is notified of the following : Ochiai/Brouwer Rejoinder Policy:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicant is required to insert on Page 2, after line 26, the title:<u>BRIEF DESCRIPTION OF THE DRAWINGS.</u>

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
January 29, 2007

Dr. Herbert J. Lilling
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Group 1600 Art Unit 1657